K071570

JUN 27 2007

Attachment B
510 (k) Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).

GE Healthcare

Section a):

1. Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC division of General Electric Company
GE Medical Systems Lunar (business name)
726 Heartland Trail
Madison, WI 53717

Contact Person: James P. Raskob
Safety and Regulatory Engineering Manager
Telephone: 608-826-7425; Fax: 608-299-2132

Date Prepared: March 12th, 2007

2. Device Name: GE Lunar Body Composition Software Option
Bone Densitometer, 21 CFR 892.1170, 90-KGI

3. Marketed Device: Body Composition Software Option for Norland DEXA Bone Densitometers K973459 currently in commercial distribution.

4. Device Description: The Body Composition Software Option for GE Lunar DEXA Bone Densitometers measures the bone mineral density (BMD), lean and fat tissue mass and calculates derivative values of bone mineral content (BMC), area, soft tissue mass, regional soft tissue mass, total soft tissue mass, fat free mass, regional/total soft tissue mass ratio, % fat, region % fat, total body % fat, Android % fat, Gynoid % fat, Android/Gynoid ratio (A/G ratio) and Body Mass Index (BMI). The values can be displayed in user-defined statistical formats and trends with color image mapping and compared to reference populations at the sole discretion of the health care professional. The software does not require any changes to the bone densitometer nor does it require additional scanning or radiation exposure beyond the bone density scans.

5. Indications for Use:

Device Name: **Body Composition Software Option for GE Lunar DEXA Bone Densitometers**

The GE Lunar Body Composition Software option (body composition) used on GE Lunar DEXA bone densitometer scans measures the regional and whole body bone mineral density (BMD), lean and fat tissue mass and calculates derivative values of bone mineral content (BMC), area, soft tissue mass, regional soft tissue mass, total soft tissue mass, fat free mass, regional/total soft tissue mass ratio, % fat, region % fat, total body % fat, Android % fat, Gynoid % fat, Android/Gynoid ratio (A/G ratio) and Body Mass Index (BMI). The values can be displayed in user-defined statistical formats and trends with color image mapping, and compared to reference populations at the sole discretion of the health care professional.

These body composition values are useful to health care professionals in their management of diseases/conditions where the disease/condition itself, or its treatment, can affect the relative amounts of patient fat and lean tissue. The GE Lunar Body Composition Software option does not diagnose disease, or recommend treatment regimens, or quantify treatment effectiveness. Only the health care professional can make these judgments. Some of the diseases/conditions for which body composition values are

useful include nutritional disorders, overweight, obesity, weight management, eating disorders, anorexia nervosa, wasting syndrome, sarcopenia , gastrointestinal disorders, Crohn's disease, celiac disease, gastrectomy, hepatobiliary disorders, cirrhosis, gallstones, renal disorders, chronic renal failure, hemodialysis, organ transplantation, endocrinological disorders, hypopituitarism, acromegaly, Cushing's syndrome, growth hormone deficiency, bone disorders, osteoporosis, Paget's disease, osteopetrosis, pulmonary diseases, cystic fibrosis, chronic pulmonary obstructive disease (COPD), cardiovascular disease, corticosteroids therapy, hormone therapy, total parenteral nutrition (TPN), diabetes, AIDS/HIV, sympathetic dystrophy syndrome, amiotrophic lateral sclerosis, tetraplegy, Duchenne's muscular dystrophy, spinal cord injury complication. DEXA body composition is a useful alternative to hydrostatic weighing, skin fold measurements and bio-impedance estimates.

6. Comparison with Predicate Device: The Body Composition Software Option for GE Lunar DEXA Bone Densitometers is of a comparable type and substantially equivalent to the Body Composition Software Option for Norland DEXA Bone Densitometers and the GE Lunar Prodigy Total Body Software option. It has the same technological characteristics, is comparable in key safety and effectiveness features, it utilizes similar design, construction, and materials, and has similar intended uses as the predicate devices.

Section b):

1. Non-clinical Tests: The device has been evaluated for electrical and mechanical safety, and has been found to conform with applicable medical device safety standards. In vitro precision and accuracy values were computed through a series of tests on phantoms and were within design specifications.

2. Clinical Tests: No clinical tests were required to establish safety or effectiveness.

3. Conclusion: Intended uses and other key features are consistent with previously cleared bone densitometer body composition software. The design and development process of the manufacturer conforms with 21 CFR 820 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance was verified through independent evaluation with ongoing factory surveillance. The Body Composition Software Option for GE Lunar DEXA Bone Densitometers is substantially equivalent to currently marketed devices with respect to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

GE Medical Systems Lunar
% Mr. Jay Y. Kogoma
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

JUN 27 2007

Re: K071570
Trade/Device Name: Body Composition Software Option for GE Lunar DEXA Bone Densitometers
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: KGI
Dated: June 7, 2007
Received: June 8, 2007

Dear Mr. Kogoma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K071570

Attachment E

510 (k) Indications for Use

510(k) Number (if known):

Device Name: **Body Composition Software Option for GE Lunar DEXA Bone Densitometers**

The GE Lunar Body Composition Software option (body composition) used on GE Lunar DEXA bone densitometer measures the regional and whole body bone mineral density (BMD), lean and fat tissue mass and calculates derivative values of bone mineral content (BMC), area, soft tissue mass, regional soft tissue mass, total soft tissue mass, fat free mass, regional/total soft tissue mass ratio, % fat, region % fat, total body % fat, Android % fat, Gynoid % fat, Android/Gynoid ratio (A/G ratio) and Body Mass Index (BMI). The values can be displayed in user-defined statistical formats and trends with color image mapping, and compared to reference populations at the sole discretion of the health care professional.

These body composition values are useful to health care professionals in their management of diseases/conditions where the disease/condition itself, or its treatment, can affect the relative amounts of patient fat and lean tissue. The GE Lunar Body Composition Software option does not diagnose disease, or recommend treatment regimens, or quantify treatment effectiveness. Only the health care professional can make these judgments. Some of the diseases/conditions for which body composition values are useful include chronic renal failure, anorexia nervosa, obesity, AIDS/HIV and cystic fibrosis. DEXA body composition is a useful alternative to hydrostatic weighing and skin fold measurements.

Prescription Use XXX (Part 21 CFR 801 Subpart D) ~~AND/OR~~ ~~Over-The-Counter Use~~ _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071570